

rechargeable power supply, (d) selected charging rate (fast or slow), and (e) selected power supply for the receiving unit (battery only, RF energy only, or a combination of both).

Such second control means, as defined now even more clearly in amended claim 1, is not found in Schulman.

The system described in the Schulman patent is for controlling the strength of a charging magnetic field and this is very different, in its objective and operation, from applicants' claimed invention.

The system described in the Schulman patent provides means for adjusting transmitted RF power by sampling the current flowing into the implanted rechargeable battery and, if the current is too high, loading the transmitting inductor in order to reduce the RF energy field. In the Schulman system, the implanted receiver contains two inductors, a first one used to couple the RF energy used to charge the battery, plus a second one used to load down the RF power source inductor. When the charging current to the implanted battery (15) reaches a maximum value, a transistor (Q1) turns on and shorts the windings of the second inductor (18) which loads the transmitting inductor (Power Head), thereby reducing its field strength. Although this could be an effective method to modulate transmitted field strength, it has a major disadvantage in that, by shorting the second inductor within the implanted receiver, the transmitting inductor will couple into a much lower impedance thus increasing the rate of discharge of the battery powering the external RF transmitting unit and significantly reduces its useable life.

Another disadvantage in the Schulman system, is that the power induced into the second inductor is wasted (whether shorted or not) since it does not contribute to the current charging the implanted battery. This wasted power further reduces the life of the battery powering the external RF transmitting unit.

In the claimed system set forth in amended claim 1, means for adjusting the transmitted RF energy field by measuring the RF energy received at the implanted device and up-linking a signal (a hexadecimal code) which commands the external RF power source to increase or decrease, as required, the power applied to the transmitting inductor in order to adjust the RF energy field, conserves the power drained from an A.C. source or the

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rechargeable battery 62. This is now brought out even more clearly in amended claim 1.

The objective is to transmit **only** the power needed to charge the implanted rechargeable battery and not more, in order to maximize the life of the battery 62 powering the external RF transmitting unit.

Transmitted power requirements vary as a function of (a) proximity and alignment of said transmitting unit to said receiving unit, (b) the output voltage of said rechargeable battery, (c) the temperature of the rechargeable battery, (d) selected charging rate (fast or slow), and (e) selected power supply for the receiving unit (battery only, RF energy only, or a combination of both).

The Examiner considers the device of Schulman to control the level of RF energy transfer from the transmitting unit to the receiving unit relative to at least the proximity of the transmitting unit to the receiving unit, with reference to claim 5.

Although it is true that the Schulman device controls the level of RF energy as a function of proximity, the objective, design, operation and performance of the Schulman device is completely different from the claimed system as described above.

The Examiner's rejection of Claim 2 under 35 U.S.C. 103(a) as being unpatentable over Schulman U.S. Patent No. 3,942,535 in view of the Kelley et al. U.S. Patent No. 4,041,955, is respectfully traversed.

While the Kelly patent discloses the use of a titanium housing to enclose a rechargeable, implantable living tissue stimulator, Schulman and Kelly do not disclose or suggest the combination of amended claim 1 and claim 2 and claim 2 is considered patentable over Schulman and Kelly for the same reasons amended claim 1 is considered patentable over Schulman.

The Examiner's rejection of Claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Schulman U.S. Patent No. 3,942,535 in view of Jeuter et al. U.S. Patent No. 5,314,457, as this rejection may be attempted to be applied against amended claim 4, is respectfully traversed..

Schulman does not disclose the use of a temperature sensor. Jeutter et al., however, discloses the use of such means in a

related device, see lines 8-16 of column 8 of Jeutter et al.

In the Jeutter et al. device, the "charging rate" of the implanted battery is the only parameter controlled by sensing battery temperature. In the system claimed in amended claim 4, the following two parameters are adjusted as a function of battery temperature: (a) charging rate to prevent battery damage, and (b) the transmitted RF energy level in order reduce current consumption of the battery powering the transmitting unit, since the reduced charge rate allows for a reduced RF energy field. Neither the Schulman or the Jeutter patents address the power savings possible in the transmitter unit of applicants' system.

The Examiner's rejection of Claims 13 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Schulman U.S. Patent No. 3,942,535 in view of the Nordling U.S. Patent No. 4,441,498, as this rejection may be attempted to be applied to amended claims 13 and 14, is respectfully traversed.

Neither the Schulman or the Nordling patents disclose the use of "start" and "stop" keys to start and stop the recharging process. In the Schulman patent the only way to stop the charging process is to turn "off" the power to the charging unit via switch 41, rendering the charging unit useless for any other purposes, such as interrogating the "charge level" of the receiving unit or adjusting the stimulation parameters of the receiving unit.

The Nordling patent does not discuss the use of "start" and "stop" charge keys, as suggested by the Examiner, since the Nordling external device **is not used** to recharge the battery of the implanted receiving unit, but **only** to adjust the stimulation parameters of the implanted receiving unit. The keys in question in the Nordling external unit (programmer) are labeled: (a) "ON/CLEAR" which is used to turn on the power to the programmer or to clear a previously selected function once the power is on, and (b) "OFF" which is used to switch off the power to the programmer. The exclusive use of the "stop" and "start" keys to start and stop the charging function without turning off the power to the external transmitting unit is a very important and unique feature to applicants' claimed invention, in that it allows the transmitting unit to remain in the power "ON" state, allowing it to be used for other functions, such as automatically

interrogating the charge level of the receiving unit at convenient time intervals, or to make adjustments of the stimulating parameters in the receiving unit.

The Examiner's rejection of Claims 16 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Schulman U.S. Patent No. 3,942,535 is respectfully traversed.

Applicants' rechargeable power supply system and controls therein, offer several novel and useful features **not available in the prior art**, thus providing better control over the recharging process and operation of the implanted device with less involvement from the patient. The unique advantages of the claimed system over the prior art, makes it a suitable rechargeable power supply system for many implantable devices that require relatively high power to operate, thus avoiding the risks and discomfort associated with frequent replacement of the implanted device that would be necessary if a non-rechargeable battery is employed.

The indication of allowability of claims 6-9 and 11 if rewritten to overcome the rejections under 35 U.S.C. § 112 and to include all the limitations of the base claim and any intervening claims, is noted. In view of this indication of allowability, claims 6-9 and 11 have been rewritten as new claims 23-28 and have been amended to overcome the rejections under 35 U.S.C. § 112 of original claims 6-9 and 11.

Support for the language in the amended and new claims is set forth below:

**CLAIM 1 Transmitting unit:** external unit 12 in FIGS. 1, 3, 4, 5 and 6.

**Receiving unit:** implanted unit 14 in FIGS. 1, 3, 4, 5 and 6.

**RF energy transmitting means:**  $\mu$ C 26, line 70, DC/DC converter 28 and inductor 64 in FIGS. 1, 3, 4, 5 and 6.

**RF energy receiving means:** inductor 60, bridge rectifier 74 and voltage regulator 54 in FIGS. 1, 3, 4, 5 and 6.

**Rechargeable battery:** battery 44 in FIGS. 1, 3, 4, 5 and 6.

**First control means:**  $\mu$ C 26, line 70 and DC/DC

converter 28 in FIGS. 1, 3, 4, 5 and 6.

**Power source:** battery 62 in FIGS. 1, 3, 4, 5 and 6.

**Second control means:** DAC 94 in FIGS. 1, 2A, 2B, 3, 4, 5 and 6.

**CLAIM 4    Rechargeable battery:** battery 44 in FIGS. 1, 3, 4, 5 and 6.

**Temperature sensor:** thermistor 80 in FIGS. 1, 3, 4, 5 and 6.

**Signal transmitting means:**  $\mu$ C 46, encoder 500, output amplifier 501, and inductor 502 in FIGS. 1, 3, 4, 5 and 6.

**First control means:**  $\mu$ C 26, DC/DC converter 28 and inductor 64 in FIGS. 1, 3, 4, 5 and 6.

**CLAIM 6    Power source selection means:** PMOS transistors P1 and P2 plus  $\mu$ C output ports 45 and 47 in FIGS. 1, 3, 4, 5 and 6.

**CLAIM 7    Means for rectifying said RF energy:** rectifier 74 and capacitor 503 in FIGS. 1, 3, 4, 5 and 6.

**Means for regulating said high DC voltage into a lower DC voltage:** voltage regulator 54 in FIGS. 1, 3, 4, 5 and 6.

**Means for detecting the presence of said RF energy field:** inductor 60, rectifier 74, voltage regulator 54, regulator output line 50, voltage divider 76 and A/D converter 78 in FIGS. 1, 3, 4, 5 and 6.

**CLAIMS 8 and 24 At least 24 hours:** In the ABSTRACT OF THE DISCLOSURE, page 24, line 12.

**CLAIM 10    Means for controlling the level of RF energy transfer:** a closed-loop system is shown in FIGS. 1, 3, 4, 5 and 6, comprising: (a) means for measuring received RF energy level, voltage divider 76 and A/D converter 76; (b) means for up-linking commands to increase or decrease the level of RF energy been transmitted,  $\mu$ C 46, encoder 500, up-link amplifier 501 and inductor 502; (c) means for receiving and decoding said up-link commands, inductor 38, up-link amplifier 39, up-link decoder 40 and  $\mu$ C 26; (d) means for regulating the level of RF energy been transmitted,  $\mu$ C output port 70, DC/DC converter 28 and RF energy transmitting

inductor 64.

**CLAIM 11 Means for measuring the charge level of said rechargeable battery:** conductor 90, analog switch 92 and A/D converter 86 in FIGS. 1, 3, 4, 5 and 6.

**CLAIM 22 Explanation of paragraph (a):** in FIGS. 1, 3, 4, 5 and 6, transistor P1 is opened by  $\mu$ C port 47 and transistor P2 is closed by  $\mu$ C port 45. This allows receiving unit 14 and the implanted device to obtain its VDD supply from RF energy only through regulator 54 and conductor 50, up through P2 and conductor 52. Note that since P1 is open, battery 44 cannot be drained but is maintained fully charged via D/A converter 95. As described above, the charge level of battery 44 is monitored via analog switch 84 and D/A converter 86. As explained in claim 10 (above) the receiving unit senses the level of RF energy being received and up-links the appropriate command to increase or decrease the transmitted RF energy level until the RF energy coupled into the receiving unit is the minimum level required to operate: (a) voltage regulator 54; (2) D/A converter 94; (3)  $\mu$ C 46; (4) thermistor 80, analog switches 92 and 84 plus A/D converter 86 in order to maintain battery 44 fully charged.

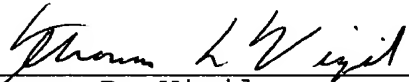
**Explanation of paragraph (b):** When the implanted device is set to operate in the "battery only" mode, the same closed-loop system described in claim 10 (above) is used to adjust the RF energy transmitted to the minimum level required to: (1) quickly recharge battery 44 and; (2) after reaching a fully charged state, to switch to a lower RF level required only to maintain said fully charged state.

**Explanation of paragraph (c):** When set to the "combination" mode, the receiving unit automatically switches to obtain its VDD supply from either battery 44 upon detecting the loss of the RF energy field, or regulator 54 upon detecting the presence of the RF energy field.  $\mu$ C 46 expects a minimum voltage level at output of D/A converter 78. When the RF energy

field is moved away from the receiving unit sufficiently to cause the voltage level at the output of D/A 78 to drop below a minimum value,  $\mu$ C 46 will quickly turn off P2 and turn on P1 so that VDD is only obtained from battery 44. Likewise, when the transmitted RF energy level rises above said minimum level, P1 is turned off and P2 is turned on so that VDD is obtained from regulator 54 instead of from the battery. Capacitor 505 prevents glitches at VDD while the switching takes place.

An earnest endeavor has been made to amend the claims to distinguish them over the prior art references cited and to otherwise place the claims in condition for allowance. An early and favorable action to that end is requested.

Respectfully submitted,

  
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